REMARKS

The Examiner has restricted the claimed invention under 35 U.S.C. §121 and 372 into the following four groups.

Group I: Claims 1-7 drawn to a method of identifying a gene having a role in diabetic nephropathy;

Group II: Claim 8, drawn to a method of using a gene having a role in the presentation of diabetic nephropathy as a diagnostic marker;

Group III: Claim 9, drawn to a method of using a gene having a role in the presentation of diabetic nephropathy as an index of disease activity and the rate of disease progression; and

Group IV: Claim 10, drawn to a method of using a gene having a role in the presentation of diabetic nephropathy as a basis for identifying drugs for use in the prevention and/or treatment of diabetic nephropathy.

Applicants note that the Examiner has failed to indicate which Group contains claim 11. Applicants presume claim 11, which depends from claim 7 falls with Group I, also containing claim 7.

Applicants elect for examination the invention of Group I, i.e. claims 1-7 and 11.

The Examiner further restricts the claimed invention to one of SEQ ID NOS:1-6. The Examiner specifies that the restriction regarding the sequence is NOT an election of species.

Applicants strongly traverse this restriction requirement as being completely improper. M.P.E.P.§803.02 states,

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
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> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 7 recites six sequences in the form of a Markush group. As such, restriction of claim 7 is guided by M.P.E.P. §803.02. Review of claim 7 reveals only six recited nucleotide sequences, all of which are fairly small in size (only one is over 500 bases, i.e. SEQ ID NO:2, which is 761 nucleotides). As such, "the members of the Markush group are sufficiently few in number or so closely

related that a search and examination of the entire claim can be made without serious burden." To facilitate the search and examination of the sequences of claim 7, attached hereto are BLAST and alignment (CLUSTAL W) analyses of SEQ ID NOS:1-6. For ease of consideration by the Examiner, attached hereto is both a full analysis (-FULL) and shortened version (-SUMMARY). The BLAST analysis was carried out using normal default settings. The shortened version contains the blast and alignment for the top scoring sequences. The CLUSTAL W alignment is shown for the most prominent scoring sequences for the BLAST analysis. In the shortened version, the homologous sequences are shortened to only include that part of the sequence that is similar to the particular SEQ ID in question. Applicants submit that given the small number of sequences, all of which are relatively small in size, and the BLAST and alignment analyses provided by Applicants, it would not be an undue burden by the Examiner to search and consider all six sequences.

In addition, all of the sequences share unity of invention as defined in M.P.E.P. §803.02. That is, all of six sequences (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. As evidenced by dependency of claim 7 on claim 1, all six sequences have the common structure of being a gene having a role in the

presentation of diabetic nephropathy. In addition, as evidenced by claims 8-10, the sequences of claim 7 all share the common utility of being a diagnostic marker, an index of disease activity or a basis for identifying drugs useful for the prevention and/or treatment of diabetic nephropathy. As such, the criteria for unity of invention of a Markush group have been met and restriction is improper. In the event that the Examiner refuses to examine SEQ ID NOS:1-6, Applicants elect with strong traverse, SEQ ID NO:1.

Attached hereto is a marked-up version of claim 7, showing all changes.

Applicants request a two (2) month extension of time for filing the present response. The required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachments: Marked-up version showing changes
Blast and alignment analyses

MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

Claim 7 has been amended as follows.

7. (Twice Amended) A method according to Claim 1, wherein the gene so differently expressed is a gene which includes a sequence selected from **the group consisting of**:

1) SEQ ID NOS: 1-3;

2) SEQ ID NO:4;

3) SEQ ID NO:5; and

4) SEQ ID NO:6.